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SOP 355 Establishing the Identity of Participants in Clinical Research

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
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1	November 2023		Updated template Clarification of scope, healthy volunteer phase 1 study ID confirmation and reference to TOPS ID for NCTU trials	James Kennedy / Louise Coke / Erika Sims

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website.

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1. Contents

2. Definitions of Terms Used / Glossary

ICH GCP	International Conference on the Harmonisation of Good Clinical Practice
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
R&D	Research and Development
SI	Statutory Instrument
SOP	Standard Operating Procedure
TOPS	The Over-Volunteering Prevention System (TOPS) is a database, free to all UK organisations undertaking Phase I trials in healthy volunteers, that aims to prevent participants from taking part too frequently in trials of new medicines.
UEA	University of East Anglia

3. Objectives

To describe the process by which staff involved in clinical research establish the identity of a potential participant or participant in clinical research in accordance with ICH GCP E6 / SI 2004/1031

4. Scope

This applies to all research trial visits completed by NNUH, UEA, and QIB staff.

5. Purpose

For healthy volunteers or volunteers with the condition under study of the clinical research trial, the delegated research staff are responsible for establishing the identity of a potential participant or participant in clinical research.

NNUH, UEA and QIB define the process of ensuring that the correct person is confirmed before sharing of information, communication and consultation and/or before the initiation of any procedure, care and/or treatment occurs.

6. Procedure for Identification

For non-CTIMPs the identity of potential participants and participants must be confirmed as follows:

- By their medical case note, if one exists and is available
- Or by accessing the appropriate NNUH electronic system **and**
- In line with any local NHS Policy on establishing patient identity (e.g. the NNUH Trust Policy for Identification of Patients ref 1604)

For CTIMPs the identity of potential participants and participants must be confirmed **before** consent using the following methods:

- Valid passport
- Valid Driving Licence
- Current university or student card
- Current young person's or senior citizen's rail card

Confirmation of identification should be documented in the consent source documents. Identification should be reconfirmed during the trial if the participant is not known to the study staff and documented in the visit source documents.

If the potential participant does not have the above photographic ID they must provide two of the following;

- Household utility bill with their name on it
- National insurance (NI) card or equivalent
- Birth certificate

For Phase 1 studies, involving healthy volunteers, identity should be confirmed in the same way as for CTIMPs, plus registration on the TOPS after consent
• Confirm identity of healthy volunteer as per CTIMP process • Consent healthy volunteer to the phase 1 trial • Register healthy volunteer on TOPS before any trial activities are completed • Registration on TOPS requires a valid passport or NI card (see the TOPS SOP)

Identification for remote research visits
Remote research visits can only be performed if allowed by the protocol and identification must by confirmed using one of the following: • In line with any local NHS Policy on establishing patient identity • In line with SOP 316 Distance (remote) consenting for Children and Neonates in Research Studies

Identification for NCTU trials
The trial should be risk assessed to determine whether participant identification is required, particularly for trials with limited safety issues.

7. References and Related Documents

References
ICH GCP E6 / SI 2004/1041
SOP 316 Distance (remote) consenting for Children and Neonates in Research Studies
The NNUH Trust Policy for Identification of Patients (Trust Docs ID 1604)
The Over-Volunteering Prevention System **https://www.hra.nhs.uk/about-us/committees-and-services/the-over-volunteering-prevention-system/**

8. Approval

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9. Training Implication

Training Implication	**No**
Actions required	• None